

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: :  
Jeffrey E. FETTERMAN, et al. : Confirmation No.: 6372  
Application No.: 10/722,262 : Group Art Unit: 3686  
Filed: November 25, 2003 : Examiner: Rajiv J. Raj

Title: A METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED WITH A  
PHARMACEUTICAL PRODUCT

**AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.111**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Amendment and Response constitutes a complete and timely reply to the Office Action mailed June 25, 2009 in the above-identified application. The following remarks are respectfully submitted.

**Amendments to the Claims** begin on page 2.

**Remarks** begin on page 14.